REMARKS

Claims 1, 4, 6, 8-9, 11-17, 48 and 51-53 remain in the present application. Claims 2-3, 5, 7, 10, 18-47, and 49-50 are cancelled.

Claims 1, 4, 6, 8, 11-12 and 16-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Song, PCT Published Application No. WO 2005/016399 A1 ("Song") in view of Talalay, U.S. Patent No. 4,063,367 ("Talalay") and Graff, D.A., U.S. Paent No. 5,316,146 ("Graff").

Claims 9, 13, 48 and 52-53 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Song in view of Talalay and Graff and further in view of Kohnert et al., PCT Published Application No. WO 2003/043673 ("Kohnert").

Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Song in view of Talalay and Graff and further in view of Lee et al., U.S. Patent No. 5,571,523 ("Lee").

Claim 51 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Song in view of Talalay and further in view of Gao et al., U.S. Patent No. 6,113,993 ("Gao").

Claim 1 has now been amended. New independent claim 54 has now been added. No new matter has been added. Reconsideration of the application in view of the amendment and following remarks is respectfully requested.

Rejection of Claims 1, 4, 6, 8, 11-12 and 16-17 under 35 U.S.C. § 103(a)

Claims 1, 4, 6, 8, 11-12 and 16-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Song in view of Talalay and Graff.

Song describes a method of making a medical device comprising (a) providing a solution comprising (i) solvent, (ii) a therapeutic agent, and (iii) an antioxidant; (b) providing a medical device substrate; (c) contacting the solution with the medical device substrate; and (d) removing the solvent from the solution to form the therapeutic-agent-containing region. The therapeutic-agent-containing region can be formed, for example, by dipping the medical device substrate into the solution followed by drying to remove the solvent. The medical device can be placed in a non-oxidizing environment subsequent to its formation; for example, the medical device can be placed into packaging that has been evacuated or into which an inert gas has been introduced. See Song, page 2, paragraph [0012], page 11, paragraph [0042], page 12, paragraphs [0045] and [0047] and page 13, paragraph [0051].

Talalay describes a method for rapidly drying liquid-solid composites and biologically active material in situ in a container. Containers are filled with a solution and placed on a conveyor which moves through a pre-drying housing or tunnel where ambient or gently warmed air is blown over the surface of the solution in the containers. The containers are then introduced into a chamber having a high vacuum on the order of about 500 microns in the chamber to complete the drying operation. A dry, positively sealed container of biologically active material which is not friable and which is well adhered to the wall of the container in which it is dried is thereby provided. See Talalay, column 1, lines 38-50, 57-59, column 2, lines 2-4, column 3, lines 22-25, column 4, lines 55-60 and column 6, lines 45-48.

Graff describes a transport container for transporting fragile articles such as test tubes or vials. The transport container comprises a first body member including a spring for providing an axial bias force to a vial supported therewith for restraining movement of the vial in a first axial direction and for urging the vial toward a second body member for proper seating therein. The second body member includes a plurality of positioning vanes which provide a yieldable restraint in a second axial direction. The first and second body members are connected to form a releasable, liquid-tight seal and joint therebetween. See Graff, the Abstract and Figs. 1 and 1a.

Independent claim 1 has now been amended so as to recite a "method of coating of a device with a substance comprising the steps of:

(a) providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing, the container and the receptacle being configured so that the device is coatable with the coating substance directly in the container, wherein an inner surface of the receptacle is coated with a layer of an inert, repelling material configured to increase a quantitative deposition of the coating substance on the device;

(b) providing a solution of the coating substance within the receptacle;

(c) inserting the device into the solution of the coating substance within the receptacle of the container, where the order of steps (b) and (c) can be reversed; and

(d) starting isothermal drying of the device while the device remains within the solution held within the receptacle of the container, thereby removing volatile components from the solution of the coating substance."

Support for the amendment can be found throughout the Specification as filed, for example, on page 23, line 30 to page 24, line 12, page 24, line 31 to page 25, line 3, page 29, lines 24-30 and Fig. 9. These sections and the Figure makes clear that the packaging container, which comprises "a receptacle for receiving the device to be coated," "is adapted such that the device is coatable directly within said packaging container." This section also makes clear that "[i]t is preferred that the inner surface of said receptacle is coated, for example with a layer of an inert, repelling such as a hydrophilic or hydrophobic material, like silicone or BPFE or a PTFE like material in the case of aqueous solutions." The "coating influences the distribution coefficient of the substance to be coated on said device between the container and said device" so that more of the substance to be coated is coated on the device. No new matter was added.

Applicants respectfully submit that none of Song, Talalay and Graff teach or suggest "providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing, the container and the receptacle being configured so that the device is coatable with the coating substance directly in the container, wherein an inner surface of the receptacle is coated with a layer of an inert, repelling material configured to increase a quantitative deposition of the coating substance on the device" and

"starting isothermal drying of the device while the device remains within the solution held within the receptacle of the container, thereby removing volatile components from the solution of the coating substance" as is now recited in independent claim 1. In contrast, Song describes a method of making a medical device comprising (a) providing a solution comprising (i) solvent, (ii) a therapeutic agent, and (iii) an antioxidant; (b) providing a medical device substrate; (c) contacting the solution with the medical device substrate; and (d) removing the solvent from the solution to form the therapeutic-agent-containing region. See Song, paragraph [0012]. However, Song does not anywhere describe "providing a container having a receptacle for receiving the device to be coated," nor does Song describe that "the receptacle of the container is coaxially located within a container housing," nor does Song describe that "the container and the receptacle [are] configured so that the device is coatable with the coating substance directly in the container," nor does Song describe that "an inner surface of the receptacle is coated with a layer of an inert, repelling material configured to increase a quantitative deposition of the coating substance on the device," nor does Song describe "starting isothermal drying of the device while the device remains within the solution held within the receptacle of the container, thereby removing volatile components from the solution of the coating substance" as is recited in independent claim 1 of the present application. None of the solvent-based techniques of Song furthermore teach the aforementioned limitations. While Song describes "dipping techniques," a person of ordinary skill in the art under reference to the description of Song would interpret "dipping techniques" consistent with the usual dictionary definition of "dip," which is to plunge briefly into a liquid, as in order to wet, coat, or saturate. See, for example, http://www.thefreedictionary.com/dip. Independent claim 1, however, requires "starting isothermal drying of the device **while the device remains within the solution held within the receptacle of the container**, thereby removing volatile components from the solution of the coating substance." Applicants submit that the Office is reinterpreting the word "dipping" in Song to mean "immersing;" i.e., "while the device remains within the solution held within the receptacle of the container," however, this limitation is simply not described in Song. Talalay does not cure this defect. Talalay does not anywhere describe "providing a container having a receptacle for receiving the device to be coated," nor does Talalay describe that "the receptacle of the container is

coaxially located within a container housing," nor Talalay describe that "the container and the receptacle [are] configured so that the device is coatable with the coating substance directly in the container," nor does Talalay describe that "an inner surface of the receptacle is coated with a layer of an inert, repelling material configured to increase a quantitative deposition of the coating substance on the device," nor does Talalay describe "starting isothermal drying of the device while the device remains within the solution held within the receptacle of the container, thereby removing volatile components from the solution of the coating substance" as is recited in independent claim 1 of the present application. Talalay does not, for example, describe a device at all. Talalay only describes a method for rapidly drying liquid-solid composites and biologically active materials in situ in a container. See Talalay, column 1, lines 48-50. The Office states that Song in combination with Talalay teaches a method for coating a device where the receptacle becomes the packaging container. See Office Action dated April 20, 2011, Detailed Action, page 6, lines 16-17. Applicants respectfully submit that said combination is not supported by either by Song or Talalay. Song in fact teaches that its medical device can be placed "in a non-oxidizing environment subsequent to its formation." For example, the medical device can be placed into packaging that has been evacuated or into which an inert gas has been introduced." See Song, page 12, paragraph [0047]. In other words, Song specifically requires that the medical device *first be formed*, and *subsequent to its formation*, that the Song medical device can *then* be placed into *packaging* that has been evacuated or into which an inert gas has been introduced. It is therefore clear that the "container" into which the medical device in Song is dipped can *never* be the packaging container because Song specifically *teaches away* therefrom. Said packaging container can, therefore, only be taught by Talalay. However, the Applicants submit that the Office does not apply the Talalay reference for this purpose. The Office specifically states that it uses Talalay for its "method for drying liquid contained in a receptacle." See Office Action of April 20, 2011, Detailed Action, page 6, line 3-6. However, if the packaging container/container as cited by the Office is not that of Song for the reasons cited above, said packaging container/container can only be provided by Talalay. However, Applicants submit that Talaly specifically *teaches away* from the present invention by expressly requiring that its dried material be *well adhered* to the container. This is in direct contrast

to the feature recited in independent claim 1 that "an inner surface of the receptacle [be] coated with a layer of an inert, repelling material configured to increase a quantitative deposition of the coating substance on the device." In contrast thereto, Talalay states that:

> "It is **essential** for the proper functioning of such reagent trays used in determining minimal inhibitory concentrations **that the active material be well adhered to its container** and not dislodged due to vibration, shaking or receipt of a blow which might occur in shipment and handling.
>
> Emphasis added. See Talalay, column 1, lines 42-47.

Talalay describes the invention further in column 6, lines 45-48. Talalay thereby states that "[t]he invention provides dry, positively sealed containers of biologically active material which is not friable and **well adhered to the wall of the container in which it is dried**." Applicants therefore submit that a person of ordinary skill in the art seeking, for example, to coat a device "with a coating substance directly in the container, wherein an inner surface of the receptacle is coated with a layer of an inert, repelling material configured to increase a quantitative deposition of the coating substance on the device" would not have considered Talalay because said reference, considered in its entirety, teaches an active material which is "well adhered to its container." Talalay considered in its entirety, therefore leads away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984), MPEP 2145(x)(D) and MPEP § 2141.01(VI). Graff also does not cure this defect. In contrast, Graff only describes a transport container for transporting fragile articles such as test tubes of vials. See Graff, the Abstract. However, Graff does not anywhere describe "providing a container having a receptacle for receiving the device to be coated," nor does Graff describe that "the receptacle of the container is coaxially located within a container housing," nor does Graff describe that "the container and the receptacle [are] configured so that the device is coatable with the coating substance directly in the container," nor does Graff describe that "an inner surface of the receptacle

is coated with a layer of an inert, repelling material configured to increase a quantitative deposition of the coating substance on the device," nor does Graff describe "starting isothermal drying of the device while the device remains within the solution held within the receptacle of the container, thereby removing volatile components from the solution of the coating substance" as is recited in independent claim 1 o the present application.

Because each of Song, Talalay an Graff are missing at least the recited elements of "providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing, the container and the receptacle being configured so that the device is coatable with the coating substance directly in the container, wherein an inner surface of the receptacle is coated with a layer of an inert, repelling material configured to increase a quantitative deposition of the coating substance on the device" and "starting isothermal drying of the device while the device remains within the solution held within the receptacle of the container, thereby removing volatile components from the solution of the coating substance" as now recited in independent claim 1, it is respectfully submitted that any combination of Song, Talalay and Graff, to the extent proper, could not render independent claim 1, or any of its dependent claims, obvious.

For at least the above reasons, reconsideration and withdrawal of the rejection to claims 1, 4, 6, 8, 11-12 and 16-17 under 35 U.S.C. § 103(a) based on Song in view of Talalay and Graff is respectfully requested.

Rejection of Claims 9, 13, 48 and 52-53 under 35 U.S.C. § 103(a)

Claims 9, 13, 48 and 52-53 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Song in view of Talalay and Graff and further in view of Kohnert.

Song, Talalay and Graff were described above.

Kohnert describes a device having osteoinductive and osteoconductive properties in vivo comprising a carrier containing calcium phosphate and an osteoinductiv protein. The device is prepared by providing a solution comprising an osteoinductive protein and a buffer and contacting

the solution with a carrier containing calcium phosphate. See Kohnert, page 6, line 27 to page 7, line 4 and the Abstract.

It is respectfully submitted that each of claims 9, 13, 48 and 52-53 properly depend from independent claim 1. As stated above, each of Song, Talalay and Graff fail to teach or suggest "providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing, the container and the receptacle being configured so that the device is coatable with the coating substance directly in the container, wherein an inner surface of the receptacle is coated with a layer of an inert, repelling material configured to increase a quantitative deposition of the coating substance on the device" and "starting isothermal drying of the device while the device remains within the solution held within the receptacle of the container, thereby removing volatile components from the solution of the coating substance" as is now recited in independent claim 1. Kohnert does not cure this defect. Kohnert describes a device having osteoinductive and osteoconductive properties in vivo comprising a carrier containing calcium phosphate and an osteoinductiv protein. The device is prepared by providing a solution comprising an osteoinductive protein and a buffer and contacting the solution with a carrier containing calcium phosphate. See Kohnert, page 6, line 27 to page 7, line 4 and the Abstract. However, Kohnert nowhere teaches or suggests the aforementioned recited limitations of independent claim 1.

Because each of Song, Talalay, Graff and Kohnert are missing at least the recited elements of "providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing, the container and the receptacle being configured so that the device is coatable with the coating substance directly in the container, wherein an inner surface of the receptacle is coated with a layer of an inert, repelling material configured to increase a quantitative deposition of the coating substance on the device" and "starting isothermal drying of the device while the device remains within the solution held within the receptacle of the container, thereby removing volatile components from the solution of the coating substance," as recited in independent claim 1, it is respectfully submitted that any

combination of Song, Talalay, Graff and Kohnert, to the extent proper, could not render independent claim 1, or any of its dependent claims 9, 13, 48 and 52-53, obvious.

For at least the above reasons, reconsideration and withdrawal of the rejection to claims 9, 13, 48 and 52-53 under 35 U.S.C. § 103(a) based on Song in view of Talalay and Graff and further in view of Kohnert is respectfully requested.

Rejection of Claim 15 under 35 U.S.C. § 103(a)

Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Song in view of Talalay and Graff and further in view of Lee.

Song, Talalay and Graff were described above.

Lee describes a method of inhibiting arteriosclerosis or smooth muscle cell proliferation by identifying an animal having an artery suspected of needing inhibition and contacting the artery with an apoptosis-inducing amount of an antioxidant such as methionine. See Lee, column 1, lines 37-40 and the Abstract.

It is respectfully submitted that claim 15 properly depends from independent claim 1. As stated above, each of Song., Talalay and Graff fail to teach or suggest "providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing, the container and the receptacle being configured so that the device is coatable with the coating substance directly in the container, wherein an inner surface of the receptacle is coated with a layer of an inert, repelling material configured to increase a quantitative deposition of the coating substance on the device" and "starting isothermal drying of the device while the device remains within the solution held within the receptacle of the container, thereby removing volatile components from the solution of the coating substance" as is now recited in independent claim 1. Lee does not cure this defect. In contrast, Lee only describes a method of inhibiting arteriosclerosis or smooth muscle cell proliferation by identifying an animal having an artery suspected of needing inhibition and contacting the artery with an apoptosis-inducing amount of an antioxidant such as methionine. See Lee, column 1, lines 37-40 and the Abstract. However, Lee nowhere teaches or suggests the aforementioned recited limitations of independent claim 1.

Because each of Song, Talalay, Graff and Lee are missing at least the recited elements of "providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing, the container and the receptacle being configured so that the device is coatable with the coating substance directly in the container, wherein an inner surface of the receptacle is coated with a layer of an inert, repelling material configured to increase a quantitative deposition of the coating substance on the device" and "starting isothermal drying of the device while the device remains within the solution held within the receptacle of the container, thereby removing volatile components from the solution of the coating substance," as recited in independent claim 1, it is respectfully submitted that any combination of Song, Talalay, Graff and Lee, to the extent proper, could not render independent claim 1, or its dependent claim 15, obvious.

For at least the above reasons, reconsideration and withdrawal of the rejection to claim 15 under 35 U.S.C. § 103(a) based on Song in view of Talalay and Graff and further in view of Lee is respectfully requested.

Rejection of Claim 51 under 35 U.S.C. § 103(a)

Claim 51 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Song in view of Talalay and further in view of Gao.

Song and Talalay were described above.

Gao teaches a method of coating a substrate with a calcium phosphate compound using plasma enhanced MOCVD. The substrate can thereby be a titanium alloy. See Gao, column 3, lines 4-8 and the Abstract.

It is respectfully submitted that claim 51 properly depends from independent claim 1. As stated above, each of Song and Talalay fail to teach or suggest "providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing, the container and the receptacle being configured so that the device is coatable with the coating substance directly in the container, wherein an inner surface of the receptacle is coated with a layer of an inert, repelling material configured to increase a

quantitative deposition of the coating substance on the device" and "starting isothermal drying of the device while the device remains within the solution held within the receptacle of the container, thereby removing volatile components from the solution of the coating substance" as is now recited in independent claim 1. Gao does not cure this defect. In contrast, Gao only describes a method of coating a substrate with a calcium phosphate compound using plasma enhanced MOCVD. See Gao, column 3, lines 4-8 and the Abstract. However, Gao nowhere teaches or suggests the aforementioned recited limitations of independent claim 1.

Because each of Song, Talalay and Gao are missing at least the recited elements of "providing a container having a receptacle for receiving the device to be coated, wherein the receptacle of the container is coaxially located within a container housing, the container and the receptacle being configured so that the device is coatable with the coating substance directly in the container, wherein an inner surface of the receptacle is coated with a layer of an inert, repelling material configured to increase a quantitative deposition of the coating substance on the device" and "starting isothermal drying of the device while the device remains within the solution held within the receptacle of the container, thereby removing volatile components from the solution of the coating substance," as recited in independent claim 1, it is respectfully submitted that any combination of Song, Talalay and Gao, to the extent proper, could not render independent claim 1, or its dependent claim 51, obvious.

For at least the above reasons, reconsideration and withdrawal of the rejection to claim 51 under 35 U.S.C. § 103(a) based on Song in view of Song in view of Talalay and further in view of Gao is respectfully requested.

New Claim 54

Applicants submit new independent claim 54 for the Office's consideration. New independent claim 54 is based on amended independent claim 1 with the additional limitation "wherein the container and the receptacle is a packaging container for the device." Support for new claim 54 can be found throughout the Specification as filed, for example, on page 23, lines 30-34 where it is provided that "the present invention provides a packaging container for a device, wherein

said packaging container is adapted such that said device is coatable directly within said packaging container. Thus, the container according to the present invention fulfills both functions, vessel for an in-situ coating process of the device (e.g. implant) and primary packaging system for long-term storage." No new matter has been added.

Applicants submit that new independent claim 54 is patentable for the same reasons set forth for independent claim 1 above. In addition thereto, Applicants respectfully submit that none of Song, Talalay and Graff teach or suggest the limitation "wherein the container and the receptacle is a packaging container for the device." In contrast, Song specifically teaches a method of making a medical device where the medical device can be placed "in a non-oxidizing environment subsequent to its formation. For example, the medical device can be placed into packaging that has been evacuated or into which an inert gas has been introduced." See Song, page 12, paragraph [0047]. Song thereby specifically requires that the medical device *first be formed*, and *subsequent to its formation*, that said medical device can *then* be placed into *packaging* that has been evacuated or into which an inert gas has been introduced. New independent claim 54, however, now requires "that the container and the receptacle [be] configured so that the device is coatable with the coating substance directly in the container," "wherein the container and the receptacle is a packaging container for the device." For the sake of clarity, new independent claim 54 provides that the device to be coated be placed in the receptacle of the container. The device to be coated is there immersed into the solution of the coating substance. Isothermal drying of the device is then undertaken while the device remains within the solution held within the receptacle of the container. The device is *not* thereafter removed from the receptacle in the container. The container and the receptacle *is* the packaging container for the device. Song does not teach or suggest this feature. As set forth above, Applicants respectfully submit that Song specifically teaches away from using the "container" as a packaging container by requiring that its device first be formed, and then subsequently placed into packaging. Talalay does not cure this defect. In contrast, the Office states that it uses Talalay for its teaching of a method for drying liquid contained in a receptacle. See Office Action of April 20, 2011, Detailed Action, page 6, line 3-6. A combination of Song and Talalay would now require that the teaching of Song, whereby the medical device is first formed and, subsequent thereto, is placed

into packaging, be ignored. As previously stated above, however, a reference must be considered in its entirety, including those parts that lead away from the claimed invention.

It is respectfully submitted that new independent claim 54 is patentable over the cited references.

CONCLUSION

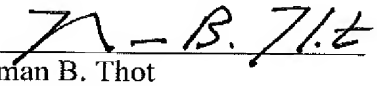
In view of the above amendments, Applicants believe the pending application is in condition for allowance.

It is believed that no fee(s) are required for this submission. Should the U.S. Patent and Trademark Office determine that additional fees are owed or that any refund is owed for this application, the Commissioner is hereby authorized and requested to charge the required fee(s) and/or credit the refund(s) owed to our Deposit Account No. 50-5256.

Favorable action is earnestly solicited.

Dated: July 19, 2011

Respectfully submitted,

By 

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